

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

NIPPON SHINYAKU CO., LTD.

14 Nishinsho-Monguchi-cho, Kisshoin, Minami-ku,  
Kyoto 601-8550, Japan

Plaintiff,

v.

DAVID KAPPOS, in his official capacity as Under  
Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark  
Office

Office of General Counsel  
United States Patent and Trademark Office  
P.O. Box 15667, Arlington, VA 22215

Madison Building East, Room 10B20  
600 Dulany Street, Alexandria, VA 22314,

Defendant.

No.

**COMPLAINT**

Plaintiff, Nippon Shinyaku Co., Ltd. ("NS"), by its attorneys, alleges that:

**Nature of Action**

1. This is an action under 35 U.S.C. § 154(b) for review of patent term adjustments made by the Director of the United States Patent and Trademark Office ("PTO"), and for alternative relief under the Fifth Amendment to the United States Constitution.

2. The PTO's patent term adjustments challenged in this case were based on an erroneous interpretation of 35 U.S.C. § 154(b) that the United States Court of Appeals for the Federal Circuit rejected in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) ("*Wyeth*").

### **Jurisdiction and Venue**

3. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 1361.

4. Venue is proper in this District under 35 U.S.C. § 154(b)(4)(A) and 28 U.S.C. §1391(e).

### **The Parties**

5. Plaintiff NS is a Japanese corporation having a principal place of business in Kyoto, Japan.

6. Defendant Kappos is the Under Secretary of Commerce for Intellectual Property and Director of the PTO.

### **Factual Background**

7. Plaintiff is the owner of U.S. Patent Nos. 7,205,302 (the "'302 patent") and 7,494,997 (the "'997 patent"), which are in full force and effect. The '302 patent issued on April 17, 2007, and was granted a patent term adjustment by the PTO under 35 U.S.C. § 154(b). The PTO's adjustment extended the '302 patent's term an additional 344 days. The '997 patent issued on February 24, 2009, and was granted a patent term adjustment by the PTO under 35 U.S.C. § 154(b). The PTO's adjustment extended the '997 patent's term an additional 99 days.

8. On January 7, 2010, the United States Court of Appeals for the Federal Circuit issued an opinion in *Wyeth* holding that the PTO's long-standing method of calculating patent term adjustments under 35 U.S.C. § 154(b) was erroneous.

9. The '302 patent is entitled, under *Wyeth*, to a patent term adjustment of 500 days rather than the 344 days originally calculated by the PTO.

10. The '997 patent is entitled, under *Wyeth*, to a patent term adjustment of 319 days rather than the 99 days originally calculated by the PTO.

11. The miscalculation by the PTO has wrongly taken and deprived NS of valuable intellectual property rights including the right to exclude others from making, using, offering to sell, or selling in the U.S. or importing into the U.S. the invention claimed in the '302 patent for 156 additional days.

12. The miscalculation by the PTO has wrongly taken and deprived NS of valuable intellectual property rights including the right to exclude others from making, using, offering to sell, or selling in the U.S. or importing into the U.S. the invention claimed in the '997 patent for 220 additional days.

13. The PTO issued interim rules for patentees to request recalculation of their patent term adjustments for patents that had issued within 180 days of the *Wyeth* decision.

14. The PTO has not provided a route by which NS could receive its rightful patent term adjustments for the '302 and '997 patents.

15. Nevertheless, on July 6, 2010, NS submitted requests for reconsideration and recalculation of the patent term adjustments for the '302 and '997 patents, and for the PTO to issue certificates of correction reflecting the correct patent term adjustments for the '302 and '997 patents. Those requests remain pending.

**Count 1 – Appeal of Patent Term Adjustment Determination  
(35 U.S.C. § 154(b)(4)(A))**

16. Plaintiff repeats and realleges paragraphs 1-15 of this Complaint as if fully stated herein.

17. Plaintiff is dissatisfied with the determinations made by Defendant under 35 U.S.C. § 154(b)(3) as to the patent term adjustments for the '302 and '997 patents.

18. The Defendant's determinations of the patent term adjustments for the '302 and '997 patents were arbitrary, capricious, an abuse of discretion, or otherwise not in accordance

with law under 5 U.S.C. § 706(2)(A) because the determinations relied upon the method of calculation rejected in *Wyeth*.

19. The Defendant's determinations of the patent term adjustments for the '302 and '997 patents were in excess of statutory jurisdiction, authority, or limitations, or short of statutory right under 5 U.S.C. § 706(2)(C) because the determinations relied upon the method of calculation rejected in *Wyeth*.

**Count 2 – Takings Clause**

20. Plaintiff repeats and realleges paragraphs 1-19 of this Complaint as if fully stated herein.

21. To the extent that no relief is available under Count 1, the Defendant's determinations of the patent term adjustments for the '302 and '997 patents violated the Takings Clause of the Fifth Amendment of the U.S. Constitution.

**Count 3 – Due Process**

22. Plaintiff repeats and realleges paragraphs 1-21 of this Complaint as if fully stated herein.

23. To the extent that no relief is available under Counts 1 or 2, the Defendant's determinations of the patent term adjustments for the '302 and '997 patents violated the Due Process Clause of the Fifth Amendment of the U.S. Constitution.

WHEREFORE, Plaintiff requests that this Court:

a. Issue an Order changing the period of patent term adjustment for the '302 patent to 500 days and requiring Defendant to alter the term of the '302 patent to reflect the changed adjustment;

b. Issue an Order changing the period of patent term adjustment for the '997 patent to 319 days and requiring Defendant to alter the term of the '997 patent to reflect the changed adjustment;

c. And grant such further and other relief as this Court deems just and proper.

Dated: July 6, 2010

Respectfully submitted,

M. Miller Baker

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*ATTORNEYS FOR PLAINTIFF  
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